Claims

1. A composition selected from the group consisting of a polyalkylene glycol (PAG), a PAG derivative and a PAG conjugate, wherein said composition is in particulate form, and wherein said composition has a residual solvent content of 200 ppm or less and a volume mean particle diameter of 25 μm or less.

2. The composition of claim 1, wherein the residual solvent content is 150 ppm or less.

3. The composition of claim 2, wherein the residual solvent is not detectable.

4. The composition of claim 1, wherein the volume mean particle diameter is 10 μm or less.

5. The composition of claim 1, wherein the particles have a volume mean diameter spread of 2.4 or less.

6. The composition of claim 1 which is in the form of a free flowing powder.

7. The composition of claim 1, which contains 2.5 % w/w or less of impurities.

8. The composition of claim 1, which is a PAG or a PAG derivative.

9. The composition of claim 8, which is an activated PAG containing one or more reactive functional groups X on the main polymer chain(s) and/or at its terminae, where X is an activating group which facilitates subsequent conjugation of the polymer to another substance.

10. The activated PAG of claim 9, wherein X is selected from the group consisting of an ester, aldehyde, aldehyde precursor, acetal, maleimide, benzotriazole carbonate, carboxyl and derivatives thereof.

11. A composition comprising a covalently bound conjugate of an activated PAG, and an active substance Z, said composition in particulate form wherein said composition has a residual solvent content of 200 ppm or less and a volume mean particle diameter of 25 μm or less.

12. The composition of 11, wherein the active substance Z is selected from the group consisting of pharmaceutically and nutraceutically active substances.

13. The composition of claim 12, wherein the active substance Z is selected from the group consisting of proteins, peptides and polypeptides.

14. The composition of claim 11, wherein the active substance Z has a low aqueous solubility.

15. The composition of claim 11, which has an aqueous solubility of at least 300 mg/ml at room temperature.

16. The composition of claim 12, wherein the active substance Z is a pharmaceutically active substance and retains at least 95 % of its original activity after having been processed into particles, or regains that activity on resolvation of the particulate conjugate.

17. The composition of claim 1 selected from the group consisting of polyethylene glycol (PEG) and derivatives and conjugates thereof.

18. The composition of claim 1, which has been prepared in particulate form using a GAS particle formation process.

19. The composition of claim 18, which has been prepared in particulate form using a Nektar™ SCF particle formation process in which a compressed fluid anti-solvent is used simultaneously both to extract a fluid vehicle from, and to disperse, a solution or suspension containing composition in the vehicle.

20. The composition of claim 18, which has been prepared in particulate form using a GAS particle formation process and which has not been subjected to subsequent evaporative air drying at a temperature higher than ambient.

21. The composition of claim 10 wherein X is an N-hydroxysuccinimidyl (NHS) ester.

22. A method for forming particles of a target substance which comprises a composition selected from the group consisting of a polyalkylene glycol (PAG) and a

derivative and a conjugate thereof, which method comprises carrying out a GAS process on a solution or suspension of the target substance in a fluid vehicle and using as the anti-solvent fluid a compressed fluid which at the point of its contact with the target substance in the fluid is at a temperature of 25 °C (298 K) or below.

23. A method for forming particles of a target substance selected from the group consisting of one or more polyalkylene glycols (PAGs) and derivatives and conjugates thereof, which method comprises carrying out a GAS process on a solution or suspension of the target substance in a fluid vehicle.

24. The method of claim 22, wherein the anti-solvent fluid used in the GAS process is a compressed fluid which at the point of its contact with the target substance in the fluid vehicle is at a temperature of 25 °C (298 K) or below.

25. The method of claim 22, wherein the GAS process is a Nektar™ SCF particle formation process in which a compressed fluid anti-solvent is used simultaneously both to extract a fluid vehicle from, and to disperse, a solution or suspension containing the target substance, or a precursor thereof, in the vehicle.

26. The method of claim 22, wherein the composition is selected from the group consisting of polyethylene glycol (PEG), polypropylene glycol (PPG), and copolymers derivatives, conjugates and mixtures thereof

27. The method of claim 23, wherein the target substance is selected from the group consisting of PEG, PEG derivatives, PEG conjugates, and mixtures thereof.

28. The method of claim 22, wherein the PAG derivative is an activated PAG containing one or more reactive functional groups X on the main polymer chain(s) and/or at its terminae, where X is an activating group which facilitates subsequent conjugation of the polymer to another substance.

29. The method of claims 22, wherein the PAG conjugate is an activated PAG, covalently bound to at least one active substance Z.

30. The method of claim 22, wherein the composition has a molecular weight of from 2.5 to 40 kDaltons.

31. The method of claim 22, wherein the composition has a melting point of 55 °C or lower.

32. The method of claim 22, wherein the anti-solvent fluid is liquid carbon dioxide.

33. The method of claim 22, wherein the anti-solvent fluid, at the point of its contact with the target substance in the fluid vehicle, is at a pressure above its critical pressure P_c.

34. The method of claim 22, wherein the anti-solvent fluid, at the point of its contact with the target substance in the fluid vehicle, is at a pressure of from 75 to 125 bar.

35. The method of claim 22, wherein the temperature at the point where the target substance in the fluid vehicle contacts the anti-solvent is less than 10 °C.

36. The method of claim 35, wherein the temperature is less than 5 °C.

37. The method of claim 22, which results in a reduction of the particle size of the target substance to 70 % or less of that of the starting material.

38. The method of claim 22, which is a single step process and does not involve evaporative air drying of the particles, at a temperature higher than ambient, following their formation, and which yields particles having a residual solvent content of 1000 ppm or less.

39. The method of claim 38, which yields particles having a residual solvent content of 150 ppm or less.

40. A particulate product formed using the method of claim 22.

41. A pharmaceutical composition comprising the particulate product of claim 1 and a pharmaceutically acceptable excipient.